IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK

RULE 26(f) JOINT REPORT OF PARTIES' PLANNING MEETING

1. **The following persons participated in the planning meeting:**

   a. David I. Berl, Ellen E. Oberwetter, Thomas S. Fletcher, Counsel for Regeneron Pharmaceuticals, Inc.

   b. John Pizzo, Heinz J. Salmen, Neil B. McLaughlin, Lauren M. Lesko, Steven J. Birkos, Counsel for Mylan Pharmaceuticals Inc.

2. **Discovery Plan and Case Schedule:**

   (a) *Joint Summary Statement on Case Scheduling Issues*. The parties have substantial disagreements about the proposed schedule and related case management issues. The parties' positions on these issues have been outlined in their briefing on Regeneron's Motion Requesting Expedited Status Conference, which the parties incorporate by reference here. *See* Doc. 7, 26, 41. The parties' respective case schedules are attached as Exhibit A (Regeneron's proposed schedule) and Exhibit B (Mylan's proposed schedules) to this Rule 26(f) Report. Summaries of the parties' respective positions are provided here.

   Regeneron's Summary Statement: Regeneron believes that this case brought under the Biologics Price Competition and Innovation Act ("BPCIA") should proceed expeditiously and in a phased manner so that Regeneron may obtain the statutory injunctive relief to which it is entitled under 35 U.S.C. § 271(e)(4)(D). Regeneron will be entitled to that relief upon showing that Mylan's proposed biosimilar aflibercept product will infringe one or more claims of Regeneron's patents for aflibercept (which has a brand name of Eylea®).

To that end, Regeneron proposes a June 2023 trial on a specific subset of the patents-in-suit—*i.e.*, the 12 patents identified in Regeneron's Motion Requesting Expedited Status Conference. *See* Dkt. 7, at 6. A June 2023 trial date would enable Regeneron to obtain a final judgment and the injunctive relief provided by statute. The remaining patents could be scheduled for a later trial, if necessary.

Regeneron's proposed schedule achieves multiple aims. First, it allows Regeneron to pursue statutory injunctive relief against Mylan before that relief is mooted by the anticipated expiry of Eylea®'s regulatory exclusivity in May 2024. *See* 35 U.S.C. § 271(e)(4)(D). Second, it confers on *both parties* the certainty they seek: Regeneron will know as of May 2024 whether Mylan is enjoined by statute from launching its proposed product. And Mylan, whose own stated aim is to "obtain the certainty that it seeks" (*see* Dkt. 26, at 5), will likewise know whether or not it faces a statutory injunction on Regeneron's asserted patents. Mylan's lengthy schedule proposals, by contrast, would thwart both of these aims. And Mylan's suggestion that certainty cannot be achieved because of other companies' potential, yet-to-be-filed FDA applications is both speculative and misplaced. As between the parties' competing proposals, only Regeneron's can achieve certainty for the parties in this case.

Mylan attempts to characterize Regeneron's proposed schedule as "ultra-expedited" with an "extraordinary" "9 month" schedule to trial. But Mylan's characterization ignores the extensive pre-suit "patent dance" exchange of thousands of pages of information between the parties over a series of months. For cases like this one filed under the BPCIA, the Complaint only marks the public revelation of the parties' well-developed and ongoing dispute. In this case, for example, the following events transpired before Regeneron filed its Complaint:

January 5, 2022	Mylan notified Regeneron that its BLA was accepted.
February 22, 2022	Regeneron notified Mylan of patents that may be asserted against it under 42 U.S.C. § 262(l)(3)(A)
April 4, 2022	Mylan transmitted its invalidity contentions that it described as "detailed" and made in "good faith" to Regeneron pursuant to 42 U.S.C. § 262(l)(3)(B)
June 10, 2022	Regeneron transmitted infringement contentions to Mylan pursuant to 42 U.S.C. § 262(l)(3)(C)

In a typical patent case, these types of activities—including the exchange of both infringement and invalidity contentions—occur following the filing of the complaint. Here, however, they largely occurred before the filing of Regeneron's Complaint on August 2, 2022. Only by ignoring these extensive pre-suit disclosures can Mylan inaccurately characterize Regeneron's proposed schedule as "ultra-expedited."

Mylan's criticism that Regeneron's proposed schedule is "unprecedented" is likewise misplaced. If Mylan is suggesting that the proposed schedule is "unprecedented" for patent cases, Mylan is wrong. For example, *Verizon Services Corp. v. Cox Fibernet Virginia, Inc.* was tried nine months after the complaint was filed. No. 08-cv-157 (E.D.

Va.). And it also had substantial "size and complexity," with a complaint involving eight patents comprising 270 claims. *Id.*, ECF 36 at 1. The case nonetheless proceeded to a 10-day jury trial within the same timeframe Regeneron proposes—and without the benefit of any pre-suit "patent dance" disclosures like those that have already occurred here. *Id.*, ECF 243-310. Patent disputes before the International Trade Commission also regularly proceed to a final hearing (bench trial) in an expedited manner, in order to afford patentees the opportunity to obtain statutory relief, and demonstrate the feasibility of doing so. For example, in *Certain High-Density Fiber Optic Equipment and Components Thereof*, ITC-337-TA-1194, the parties proceeded to a four-day hearing on multiple patents in six months. *See* Schedule, Order No. 6 (May 4, 2020). Likewise, patents from five distinct patent families proceeded to a final hearing in nine months in *Certain Road Milling Machines and Components Thereof*, ITC-337-TA-1067. *See* Compl. (July 19, 2017); Schedule, Order No. 6 (Oct. 5, 2017).

If Mylan instead is arguing that such a schedule is "unprecedented" for complex litigation more generally, that too is inaccurate. Indeed, during the period that Mylan has been advocating against Regeneron's proposed schedule and rejecting its requests to participate in early information exchanges, nearly the entirety of the multi-billion-dollar *Twitter, Inc. v. Musk* case will have transpired, including fact and expert discovery.[1] While Mylan baldly asserts that Regeneron's proposed schedule for an early trial of selected patents would deprive it of due process, it cites no authority, because it has none. Mylan's proposals would, however, deprive patent owners like Regeneron from the statutory injunctive relief that Congress saw fit to provide for in the BPCIA.

Regeneron is prepared to move this case quickly toward a June 2023 trial date. The steps Regeneron has taken to date, and invited Mylan to take, demonstrate that this can be achieved.

- Regeneron has identified to Mylan a subset of Regeneron's patents for a proposed trial in June 2023 that will allow Regeneron to obtain statutory injunctive relief.
- The parties already have exchanged patent infringement and invalidity contentions pursuant to the statutory, pre-suit schedule.
- Regeneron informed Mylan weeks ago that it was prepared to make a substantial document production to Mylan, even without Requests for Production (which Mylan in any event has yet to serve). That production includes Regeneron's BLA and clinical study reports, inventor lab notebooks, and custodial ESI.
    - The only reason Regeneron has not yet made this production is that Mylan did not review and comment on Regeneron's proposed protective order (which Regeneron sent to Mylan on August 23) for three full

[1] That case was filed on July 12, 2022, with trial commencing October 17, 2022.

weeks. It finally supplied comments last week, and the parties intend to meet and confer regarding open issues.

- Regeneron has already served its First and Second Sets of Requests for Production and First Set of Interrogatories on Mylan.
- Regeneron served its Initial Disclosures on Mylan on September 20, 2022, well in advance of the October 10, 2022 due date.

During the parties' Rule 26(f) conference, Regeneron made perfectly clear that it is prepared to reach reasonable agreements on numbers of fact witnesses and the numbers and use of experts so that the parties can ready the case for trial by next summer. Mylan's speculation about unwieldy expert discovery will not come to pass with the imposition of reasonable case management limits.

Mylan complains that Regeneron should have moved the pre-suit patent dance process more quickly. But the same statute that permits a patent owner to obtain statutory injunctive relief prescribes presumptively reasonable time periods for the exchange of information through the patent dance, which Regeneron not only followed, but truncated somewhat. In any event, even if Regeneron had shaved marginal additional time off of the exchange timelines, Mylan was never going to agree to a schedule that would allow Regeneron to achieve the statutory relief that it seeks. Rather, Mylan wants a trial more than two years from now.

Regeneron has taken every reasonable step to position this case for the statutory relief that it seeks. Its proposed schedule is the only one that will serve the parties' ability to achieve statutory relief and commercial certainty on a logical timeline. Regeneron requests that the Court enter the schedule set forth on Exhibit A and is prepared to discuss at the status conference case management tools for achieving it.

Mylan's Summary Statement: As Mylan has already set forth, Regeneron's extraordinary, and unprecedented, request with regard to the schedule is based on a plainly false premise, i.e., that Regeneron requires an ultra-expedited schedule to obtain relief under 35 U.S.C. § 271(e)(4)(D). As set forth in Mylan's opposition brief (Dkt. No. 26), Regeneron's premise is false and its proposal is unreasonable for at least six reasons:

- *First*, Regeneron's 9 month-to-trial schedule is neither appropriate nor feasible given the size and complexity of the disputed issues. The 24 asserted patents stem from at least 11 separate patent families with 33 unique inventors, and involve a wide range of different subject matters, each of which on its own could constitute an entire, full-fledged litigation taking approximately two years or more. Regeneron's breakneck schedule would inevitably deprive Mylan of its due process rights to reasonable discovery and a fair trial.[2] (*Id*. at 2, 6-9).

[2] Regeneron also suggests above that the pre-suit BPCIA statements constitute the parties' complete infringement and invalidity contentions – not so. The BPCIA exchanges were never intended to replace an accused infringer's ability to take discovery on, and more fully develop in

- *Second*, Regeneron's ultra-expedited schedule is without precedent. Indeed, Regeneron has been unable to point to any other analogous pharmaceutical patent case where in 9 months the parties litigated issues of non-infringement and patent invalidity on 24 patents (currently comprising over 330 asserted claims), or even Regeneron's proposed subset of 12 patents (currently comprising over 200 asserted claims). (*Id*. at 6-9, 12 & n.7). It simply has not been done before, for many practical reasons Regeneron ignores here. The cases that Regeneron cites are not remotely on point and did not cover nearly the same number of patents, claims, or contested issues that the parties expect to need to address in this case, or the wide-ranging subject matter covered by the current patents-in-suit (methods of treating 4 different, separate indications; methods of purifying proteins; oxidized species of aflibercept; protein formulations; cell culture media and cell culture methods; cell line patents; DNA analysis patents; etc.) The only district court patent case cited by Regeneron is a 14-year old telecom case involving only 8 patents, where 4 of the patents had been previously litigated, and where trial was conducted on only 14 asserted claims from 6 of the originally-asserted patents. Regarding Regeneron's ITC citations, the fact that Regeneron has to go outside the Article III courts and cite to decisions from an executive branch forum with different rules and procedures, only underscores how extraordinary their proposed schedule is. One of those ITC cases involved only 4 related and overlapping patents (*High-Density Fiber Optic*), and the other went to trial on only 4 patents and 15 claims (*Road Milling Machines*). Further, Regeneron, on the evening of September 21, 2022, inserted two additional patents (design patents directed to packaging) into the parties' BPCIA negotiations, and waited nearly 30 days to do so.[3] Regeneron clearly has no intention of streamlining or efficiently litigating this case.

- *Third*, despite Regeneron's suggestion that it is prepared to expedite discovery,[4] during the parties' conference Regeneron was unable to answer basic questions

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litigation, its non-infringement and patent invalidity and unenforceability defenses; especially in a case like this one, where the asserted patent portfolio comprises many dubious patents directed to obvious and non-novel subject matter. *See Genentech, Inc. v. Amgen Inc.*, 17-cv-1407, Memorandum Opinion (Dkt. No. 626) at 12-13 (D. Del. Feb. 11, 2020) (denying plaintiff's request to preclude defendant from asserting case contentions not disclosed in the patent dance because "[n]othing in § 262(*l*)(9)(B) or in any other provision of the BPCIA limits the defenses an applicant can assert in such an action").

[3] The patents issued August 23, 2022. Regeneron waited nearly the entire 30-day statutory period to inform Mylan that it intended to supplement its 42 U.S.C. § 262(*l*)(3)(A) patent list pursuant to § 262(*l*)(7).

[4] Regarding the protective order, Regeneron told Mylan on August 2 that it would provide a draft protective order; Regeneron took three weeks to provide a draft, finally providing one August 23;

about how it realistically intends to complete discovery in time to take this case to trial in 9 months, including:

- Whether it represents each of the inventors of the patents-in-suit and will be able to make them available for deposition;

- Whether Regeneron intends to make use of experts in the *Markman* claim construction phase of the case, which Regeneron's proposal only allows 1.5 months for (from opening briefs through hearing);

- Whether Regeneron will limit its use of experts in the expert discovery phase of the case (Regeneron used 5 expert witnesses in a recent *inter partes* review challenge of a single patent); and

- Which claims, and/or how many claims, Regeneron intends to assert from its patents-in-suit (presumably Regeneron does not intend to assert 200+ claims at trial).

- *Fourth*, Regeneron's proposal provides it the unilateral and highly prejudicial advantage of holding the remaining patents over Mylan's head, effectively threatening to assert them in piecemeal fashion on the eve of trial or product launch. And while Mylan has remained open to discussing realistic compromise proposals, Regeneron has been unable (or unwilling) to answer basic questions about how it intends to handle the 12 remaining patents that it has asserted but does not want to immediately litigate, or questions about whether there would be any limitation on which patents Regeneron could rely upon in any future request for preliminary injunctive relief. (*Id.* at 13-14). Indeed, in its above summary, Regeneron is still unable to commit to a proposal or explain what its intentions are with respect to the remainder patents and how it intends to proceed with them, other than to suggest that the parties can engage in yet another, separate litigation, involving discovery and another trial, after having just rushed through discovery and trial on the first set of patents. Thus, Regeneron's proposal improperly seeks to create unnecessary uncertainty for Mylan, and any suggestion otherwise is simply incorrect.

- *Fifth*, Regeneron's claim that it needs to have a final court decision by May 2024 to obtain injunctive relief ignores the statutory framework and disregards the practical realities of BPCIA litigation. (*Id*. at 2-3, 9-12) (BPCIA creates a defined window for a patent owner to seek preliminary injunction and does not

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Mylan provided its proposed revisions September 13, a not unreasonable amount of time given the highly confidential and sensitive nature of the material that Mylan anticipates producing in this litigation and the restrictions that Regeneron had placed on Mylan's counsel in its original draft; Regeneron returned a draft September 23. All told, Regeneron had the draft protective order in its possession at least 31 days, to Mylan's 21 days.

prevent that patent owner from seeking a permanent injunction after an adjudication of infringement). Indeed, several other companies have publicly announced plans for aflibercept biosimilars, but given time is running out, it would be highly unlikely for Regeneron to be able to litigate the asserted patents against these other biosimilar manufacturers on a timeline that will allow a final court decision by the expiration of Regeneron's EYLEA exclusivity in May 2024. These circumstances undermine Regeneron's claim that it requires §271(e)(4)(D) relief against Mylan before that date, and Regeneron continues to ignore the other relief that Congress has provided to reference product sponsors in 35 U.S.C. § 271(e)(4).

- *Sixth*, Regeneron's pleas for urgency now, stand in stark contrast to Regeneron's approach in the patent dance, where Regeneron made little effort to expedite that process, and where Regeneron allowed the parties' patent dance to run on for ***209 days*** with no mention to Mylan of Regeneron's purported need, or its plans, for seeking such an expedited litigation schedule. (*Id.* at 11-12). Further, at least 120 of those days were solely under Regeneron's control to self-expedite, yet they chose not to. Regeneron's description of the BPCIA exchanges as somehow sufficient to replace discovery and litigation reveals its true intent and the lopsided nature of Regeneron's proposal. While Mylan did indeed produce the BLA and everything that Regeneron needs to make its infringement case, Regeneron has produced nothing to Mylan, and no discovery has been taken yet regarding the invalidity and unenforceability of Regeneron's patents. These are key issues that stand to loom large in this litigation, where the lack of inventiveness evident throughout Regeneron's patents and the issues with how Regeneron obtained its patents will be the subject of much discovery—discovery to which Mylan is entitled. Regeneron also entirely disregards the expert phase of the litigation, where, as Mylan has indicated, a wide variety of subject matter areas will be addressed, likely requiring a multitude of different expert witnesses (as indicated above, Regeneron brought 5 expert witnesses into a recent, and relatively straightforward, *inter partes* review challenge of a single one of Regeneron's dosing patents: three ophthalmologists, a molecular biologist, and an economist).

Thus, in view of the myriad issues with Regeneron's proposed schedule, Mylan offered to Regeneron during the parties' conference two reasonable alternative counter-proposals for addressing all asserted patents-in-suit, on timelines that also are expedited, but still provide the parties and the Court with sufficient time to address all issues expected to arise over the course of this litigation:

- Mylan Proposal 1 provides the parties with a typical, but accelerated, 24 month-to-trial schedule (September 2024) and includes all 24 patents-in-suit. To provide for a manageable litigation and trial schedule, Mylan Proposal 1 assumes that Regeneron will be required to narrow the litigation to a reasonable number of asserted claims, and to do so early in the litigation (i.e., before claim

construction proceedings begin) so parties' and the Court's resources are not unnecessarily strained. (*See, e.g.*, Exhibit B).

- Mylan Proposal 2 provides the parties with a more expedited schedule, with trial by December 2023, but requires Regeneron to reduce the asserted patents and claims to reasonable numbers, i.e., 8 patents and 20 claims.[5] Mylan Proposal 2 also requires that Regeneron limit any future requested injunctive relief to only the reduced patents and asserted claims, and that Regeneron provide certainty on the remaining patents, e.g., through covenants-not-to-sue, or by voluntarily dismissing the excess patents from suit. (*See, e.g.*, Exhibit B).

Mylan presented both proposals to Regeneron during the parties' Rule 26(f) conference, as well as in writing after the conference. Regeneron made no attempt to negotiate with Mylan regarding its counter-proposal schedules.

(b) *Discovery will be needed on these subjects and topics related to these subjects*:

- Whether Mylan's proposed biosimilar product will infringe Regeneron's patents

- Whether Regeneron's patents are valid and/or unenforceable

(c) *Dates for commencing and completing discovery*: The parties agree that discovery commenced on August 31, 2022, upon conclusion of their Rule 26(f) conference.

- *Regeneron's position:* Regeneron asked Mylan to accept discovery requests in advance of the Rule 26(f) conference date; Mylan declined. Regeneron has proposed that fact discovery conclude on December 15, 2022. Regeneron has already served discovery requests upon Mylan to facilitate such a deadline,

[5] This proposal is similar to how other BPCIA suits handled litigations involving other 20+ asserted patents. *See, e.g.*, *Genentech, Inc. v. Amgen Inc.*, 17-cv-01407, Amended Scheduling Order (Dkt. No. 201) at 3 (D. Del. Oct. 30, 2018) (reduction of asserted patents from 26 to 8, and limiting the number of asserted claims to 25 for claim construction and trial); *Genentech, Inc. v. Pfizer Inc.*, 17-cv-01672, Scheduling Order (Dkt. No. 48) at 5 (D. Del. Nov. 1, 2018) (40 patents-in-suit were reduced to 10 patents with a maximum of 2 claims per patent against each group of defendants in related litigations; of the 10 patents, at least 6 of the patents must be the same across all defendants in related litigations, with no more than 30 claims in total); *Genentech, Inc. v. Celltrion Inc.*, 18-cv-00095, Scheduling Order (Dkt. No. 70) at 5 (D. Del. Nov. 1, 2018) (same with respect to reduction from 40 patents-in-suit); *Genentech, Inc. v. Amgen, Inc.*, 18-cv-00924, Scheduling Order (Dkt. No. 44) at 4 (D. Del. Nov. 1, 2018) (same with respect to reduction from 37 patents-in-suit); *Genentech, Inc. v. Celltrion, Inc.*, 18-cv-01025, Scheduling Order (Dkt. No. 34) at 5 (D. Del. Nov. 1, 2018) (same with respect to reduction from 40 patents-in-suit); *Genentech, Inc. v. Samsung Bioepis Co., Ltd.*, 18-cv-01363, Scheduling Order (Dkt. No. 26) at 5 (D. Del. Nov. 1, 2018) (same with respect to reduction from 22 patents-in-suit).

and has informed Mylan that the Requests for Production that it has served to date encompass most of the documents it intends to seek.

- *Mylan's position*: Mylan has proposed that fact discovery conclude on June 30, 2023 under Mylan Proposal 1 or April 14, 2023 under Mylan Proposal 2. Regeneron's discovery requests to date are limited to a handful of requests targeted to Mylan's samples and manufacturing schedule. The parties have yet to serve full sets of requests for production, interrogatories, and/or requests for admission. Mylan intends to serve all three in due course.

3. Issues Regarding Disclosure and Discovery:

a. *Initial Disclosures:* The Court has ordered an initial disclosure date of October 10, 2022. Doc. 19.

- Regeneron served its initial disclosures on Mylan on September 20, 2022. It proposed Mylan do the same, but Mylan declined.

- Mylan is prepared to adhere to the timelines already set forth in the Court's First Order. (Dkt. No. 19).

b. Maximum number of interrogatories by each party to another party, along with the dates the answers are due:

- Regeneron proposes that the default number of interrogatories be applied.

- Mylan proposes, given that Regeneron chose to assert 24 patents, that Mylan be permitted to serve interrogatories such that each interrogatory be understood by Regeneron to include an obligation to respond with regard to each patent-in-suit, and where said interrogatory shall not be objected to as having multiple sub-parts due to the fact that each patent-in-suit is included in said interrogatory. Mylan presented this proposal to Regeneron during the parties' conference. Alternatively, Mylan proposes that Mylan be granted, in addition to the default number, one additional interrogatory for each patent-in-suit (i.e., 25 + *n*, where *n* is the number of patents still being asserted at the time the scheduling order issues).

c. *Maximum number of depositions*.

- Regeneron proposes that the parties be entitled to equal numbers of depositions, and that the number should be 12 depositions each, with any additional fact depositions taken only by agreement between the parties or upon a showing of substantial need. Mylan said during the parties' Rule 26(f) conference that it was unlikely to take all of the inventors' depositions, and giving the parties an unequal number of witnesses would

permit Mylan to inflict disproportionate costs and disruption to Regeneron's personnel and business.

- Mylan proposes that each party be bound by the limitations of Fed. R. Civ. P. 30, with the exception that, given that Regeneron chose to assert 24 patents having 33 individual inventors, the depositions of the inventors of the patents-in-suit not count against the number of depositions Mylan is entitled to under Fed. R. Civ. P. 30. During the parties' conference, Mylan presented this proposal to Regeneron. Mylan also explained that it was willing to work with Regeneron in limiting the number of inventor depositions, including through attempting to identify through discovery which inventors are most likely to be able to provide relevant and discoverable information. Regeneron's concerns about an unequal number of witnesses makes no sense in this case - Mylan is not asserting any patents against Regeneron, and thus has no inventors to offer for deposition. Regeneron's concerns about "inflict[ing] disproportionate costs and disruption" could have been addressed by limiting the asserted patents, and could still be addressed through Mylan's proposal, which calls for covenants not to sue and/or dismissals of patents that Regeneron is not interested in litigating.

d. *Maximum number of requests for admission, along with the dates responses are due:* The parties believe that it is premature to set a number of requests for admission and will seek guidance from the Court if they cannot agree to a number.

e. *Protective Order*: Regeneron sent Mylan a proposed protective order on August 23, 2022 and Mylan provided its comments on September 13, 2022. Regeneron provided its further comments on September 23, 2022. The parties hope to reach agreement on the content of such an order and submit it for the Court's approval soon.

f. *Service by email*: The parties have agreed that requests for written discovery and notices of deposition may be served by the parties on each other by email.

4. Issues Regarding Trial:

a. *Regeneron's position*: Regeneron has proposed that the Court schedule a trial for June 2023 with respect to no more than twelve of the asserted patents. If trial is held before the expiration of regulatory exclusivity and Mylan cannot yet launch its biosimilar aflibercept product, this will be a bench trial. Regeneron proposes that the Court calendar 8 trial days for the trial. Whether an additional trial on any remaining patents is even necessary can be addressed following this trial.

b. *Mylan's position*: Mylan is proposing that the Court schedule a trial at its convenience, by or about September 2024 under Mylan Proposal 1, or by or about

December 2023 under Mylan Proposal 2. Mylan's position on the number of days depends upon the number of patents and claims being asserted by Regeneron, which Regeneron has not been willing to provide certainty on. Under Mylan Proposal 1, Mylan proposes a 10-15 day bench trial; under Mylan Proposal 2 Mylan proposes a 8-10 day bench trial. Mylan's position is that Regeneron's proposal to serially engage in (at a minimum) two large, multi-patent litigations and trials, imparts unnecessary delay, complexity, and uncertainty into this matter.

5. Local Rule 16.01(b)(1-5) and 16.01(c)

(a) *Complex Case Monitoring*.

- *Regeneron's position*: Regeneron proposes that this case is complex and case-specific monitoring would be useful to ensure that the case remains on schedule. Regeneron proposes that the Court hold status conferences every 3-4 weeks depending on the schedule that is entered, so that the parties are dissuaded from interposing discovery objections that would jeopardize the trial date.

- *Mylan's position*: Mylan proposes that, while this case presents complex issues often seen in patent litigation, there is no need to designate this litigation as a complex case, and that the Court need not be burdened with status conferences every 3-4 weeks at this time. Both parties are sophisticated and have been involved in numerous patent litigations; to the extent judicial intervention is required at any point, the parties have access to the discovery dispute procedures provided for under the applicable Federal and Local rules. Moreover, Regeneron's insistence that this litigation be designated a complex case runs counter to their insistence that it be taken to trial in 9 months.

(b) *Disputed Facts*. The parties have identified preliminary facts in dispute through their pre-suit patent infringement and invalidity contentions and through the Complaint and Answer. The parties will identify further disputed facts through fact and expert discovery.

(c) *Magistrate Judge*. The parties do not consent to trial by magistrate judge.

(d) *Alternative Dispute Resolution*. The parties are not averse to ADR in concept but believe it would not be useful at this point in the case. Any efforts to resolve cases of this sort are typically accomplished between in-house counsel; accordingly, the parties prefer that the Court not schedule the case for early mediation.

(e) *Electronic Discovery*. The parties have had initial discussions about ESI, anticipate that ESI will be the subject of discovery, and anticipate exchanging information about and/or negotiating appropriate custodian and search term lists that will serve as the basis for productions of ESI by both parties.

6. Scheduling Conference Agenda

The primary topics for a scheduling conference are:

- How and whether the case may be streamlined for trial
- The dates for the case schedule
- Deviations from default discovery limits
- Open issues regarding the protective order

Date: September 23, 2022

CAREY DOUGLAS KESSLER & RUBY, PLLC

/s/ Steven R. Ruby
Steven R. Ruby (WVSB No. 10752)
David R. Pogue (WVSB No. 10806)
707 Virginia Street East
901 Chase Tower (25301)
P.O. Box 913
Charleston, West Virginia 25323
(304) 345-1234
sruby@cdkrlaw.com
drpogue@cdkrlaw.com

Of Counsel:

David I. Berl (admitted *PHV*)
Ellen E. Oberwetter (admitted *PHV*)
Thomas S. Fletcher (admitted *PHV*)
Andrew V. Trask (admitted *PHV*)
Teagan J. Gregory (admitted *PHV*)
Shaun P. Mahaffy (admitted *PHV*)
Kathryn S. Kayali (admitted *PHV*)
Arthur J. Argall III (admitted *PHV*)
Adam Pan (admitted *PHV*)
Nicholas Jordan (admitted *PHV*)
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000
dberl@wc.com
eoberwetter@wc.com

STEPTOE & JOHNSON PLLC

/s/ Gordon H. Copland
Gordon H. Copland (WVSB #828)
William J. O'Brien (WVSB #10549)
400 White Oaks Boulevard
Bridgeport, WV 26330
(304) 933-8162
gordon.copland@steptoe-johnson.com
william.obrien@steptoe-johnson.com

Of Counsel (admitted pro hac vice):

William A. Rakoczy
Heinz J. Salmen
Eric R. Hunt
Neil B. McLaughlin
Jeff A. Marx
Lauren M. Lesko
Thomas H. Ehrich
Lawrence Scott Beall
Steven J. Birkos
Katie A. Boda
Abraham J. Varon
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 W. Hubbard St., Suite 500
Chicago, IL 60654
(312) 527-2157
wrakoczy@rmmslegal.com
hsalmen@rmmslegal.com
ehunt@rmmslegal.com
nmclaughlin@rmmslegal.com

tfletcher@wc.com
atrask@wc.com
tgregory@wc.com
smahaffy@wc.com
kkayali@wc.com
aargall@wc.com
apan@wc.com
njordan@wc.com

Counsel for Plaintiff Regeneron Pharmaceuticals, Inc.

jmarx@rmmslegal.com
llesko@rmmslegal.com
tehrich@rmmslegal.com
sbeall@rmmslegal.com
sbirkos@rmmslegal.com
kboda@rmmslegal.com
avaron@rmmslegal.com

Counsel for Defendant Mylan Pharmaceuticals Inc.